

REMARKS

Reconsideration of the Office Action mailed February 11, 2003, (hereinafter "instant Office Action"), entry of the foregoing amendments and withdrawal of the rejection of claims 1-8, 10, 46 and 47, are respectfully requested.

In the instant Office Action, claims 1-8, 10, 11 and 46-52 are listed as pending, claims 11 and 48-51 are withdrawn from consideration, claims 1-8, 10, 46 and 47 are listed as rejected and claim 52 is listed as allowed.

Attached hereto as Appendix A is a marked-up version of the changes made to the claims by the current amendments. Appendix A is captioned "Version with markings to show changes made".

Applicants appreciatively note that the Examiner has withdrawn the following rejections of the Office Action mailed May 20, 2002: the rejection of claims 1-8 and 10 under 35 U.S.C. §112, second paragraph in view of the amendments filed November 25, 2002; the rejection under 35 U.S.C. 103 (a) (based on U.S.C. 102(e)) of claims 1-8, 10 and 46-47 in view of Applicants' statement of Common Ownership and the objections to claims 1 and 6 in view of the amendments filed November 25, 2002.

The Examiner has rejected claim 46 under 35 U.S.C. 103(a) over Calderwood et al., WO 98/41525. Applicants respectfully traverse this rejection.

The Examiner has not established a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness there must be some suggestion or motivation to modify the reference. The Examiner has not provided any suggestion or motivation to modify WO 98/41525 to arrive at Applicants' compounds. The prior art must also teach or suggest all the claim limitations. WO 98/41525 does not teach or suggest all of the limitations of Applicants' claims.

**BASIC REQUIREMENTS OF A *PRIMA FACIE* CASE OF
OBVIOUSNESS**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable

Application No.: 09/399,083
Art Unit: 1624

expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

MPEP §2143

The Court of Appeals for the Federal Circuit has stated the following on the issue of

obviousness:

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F. 2d 1044, 1051-52, 5 USPQ 1434, 1438 (Fed. Cir. 1988), cert. denied, 109 S. Ct. 75 (1988), on remand, 13 USPQ2d 1192 (D. Conn. 1989) "Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination.": In re Stencel, 828 F. 2d 751, 755, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987) obviousness cannot be established "by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made." Alco Standard Corp. v. Tennessee Valley Authority, 808 F. 2d 1490, 1498, 1 USPQ2d 1337, 1343 (Fed. Cir. 1986), cert. dismissed, 108 S. Ct. 26 (1987) "the question is not simply whether the prior art 'teaches' the particular element of the invention, but whether it would 'suggest the desirability, and thus the obviousness, of making the combination.'"; Carella v. Starlight Archery, 804 F. 2d 135, 231 USPQ 644 (Fed. Cir. 1986); ACS Hospital Sys., Inc. v. Montefiore Hospital, 732 F. 2d 1572, 221 USPQ 929 (Fed. Cir. 1984) "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so."

Donald S. Chisum, Patents, A Treatise on the Law of Patentability, Validity and Infringement, Vol. 2, 5-218, 1992.

In making an obviousness determination, an invention must be considered as a whole. In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). The Examiner has not shown that WO 98/41525 renders obvious the any of the compounds of Applicants' claim 46. Applicants maintain that WO 98/41525 does not render claim 46 obvious.

The Examiner alleges that the reference teaches 4-amino-7H-pyrrolo[2,3-d]pyrimidin-5-yl compounds having an optionally substituted phenyl as the 5-substituent which is further attached to $-A-R_5$ wherein A is $-NH-SO_2-$ and R_5 is optionally substituted phenyl, etc. The Examiner

further states that the instant claim differs by reciting specific species that fall within the reference genus. It is well established that a prior art genus does not make a basis for a *prima facie* case of obviousness because the species falls into it. In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (“The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious”); In re Jones, 958 F2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

Based upon the foregoing, the rejection of claim 46 under 35 U.S.C. §103(a) over WO 98/41525 is obviated and should be withdrawn.

The Examiner has rejected claims 1-8, 10-11 and 46-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,001,839. The Examiner has stated that this objection may be overcome by filing a terminal disclaimer. As Applicants pointed out in the reply filed November 20, 2002, the instant application has the same chain of priority as the ‘839 patent and, thus, will expire on the same date. Both the ‘839 patent and the instant application were purchased by Abbott Laboratories from BASF Aktiengesellschaft. Applicants have recorded Assignments with the USPTO to reflect the new ownership of the ‘839 patent and the instant application. Copies of the recordation documents are attached hereto as Appendix B. A terminal disclaimer is filed concurrently herewith.

Based upon the foregoing, the rejection of claims 1-8, 10-11 and 46-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,001,839 is obviated and should be withdrawn.

The Examiner has rejected claims 6-7 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that there is insufficient antecedent basis in claim 1 for the limitations “substituted amino”, “substituted tetrazolyl”, “-S-(substituted or unsubstituted heteroaryl)” and “R_c” in claim 6. Applicants respectfully traverse this rejection.

With respect to the Examiner’s allegation that there is insufficient antecedent basis in claim 1 for the term “substituted amino” in claim 6, Applicants have amended Claim 6 to delete the term “substituted or unsubstituted amino” and add the term “NR₄R₅”.

The Examiner alleges that there is insufficient antecedent basis in claim 1 for the term "substituted tetrazolyl" in claim 6. Applicants have amended Claim 1 to include the phrase "substituted or unsubstituted" immediately preceding the term "tetrazolyl". Support for this amendment can be found, *inter alia*, on page 22, lines 9-10 of the instant specification as filed. Thus, after entry of the amendments herein there is sufficient antecedent basis for the term "substituted tetrazolyl" in claim 6.

The Examiner alleges that there is insufficient antecedent basis in claim 1 for the term "-S-(substituted or unsubstituted heteroaryl)" in claim 6. Applicants have amended Claim 1 to include the term "S-(substituted or unsubstituted heteroaryl)". Support for this amendment can be found, *inter alia*, at page 22, line 10 of the instant specification as filed. Thus, after entry of the amendments herein there is sufficient antecedent basis for the term S-(substituted or unsubstituted heteroaryl)" in claim 6.

The Examiner alleges that there is insufficient antecedent basis in claim 1 for the limitation "R_c" as a substituent to be substituted on Ring A in claim 6. Applicants have amended Claim 1 to include the terms "-C(O)NR_fR_g, R_c and CH₂OR_c" and the definitions for R_f and R_g. Support for this amendment can be found, *inter alia*, at page 22, line 13 of the instant specification as filed. Support for the definitions of R_f, R_g and R_c can be found, *inter alia*, at page 21, lines 4-27 of the instant specification as filed. Thus, after entry of the amendments herein there is sufficient antecedent basis in claim 1 for the limitation "R_c" as a substituent to be substituted on Ring A in claim 6.

Claim 1 has also been amended to correct typographic errors to reformat the variables into subscript format in the alkyl, cycloalkyl, cycloalkenyl and phenyl(alkyl) groups.

Based upon the foregoing, the rejections of claims 6-7 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are obviated and should be withdrawn.

The Examiner has rejected claims 6 and 7 under 35 U.S.C. §102(a) as allegedly being anticipated by Calderwood et al., WO 98/41525. The Examiner alleges that "the instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., page 14, lines 9-14, 22-23 etc. The instant claims include ring A to be substituted by R_c which is defined to be -W-(CH₂)_t-O-alkyl or -W-(CH₂)_t-OH wherein W is a bond and t is 0, which

compounds are identical to the reference disclosed compounds.” Applicants respectfully traverse this rejection.

The species listed on page 14, lines 9-10, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl]benzenesulphonamide, and the species listed on page 14, lines 22-23 of Calderwood et al., N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl]-4-*tert*-butylbenzenesulphonamide, do not anticipate Applicants’ claims 6 and 7 because in both of Calderwood et al.’s compounds the phenyl group which corresponds to Applicants’ Ring A is substituted by methoxy. Methoxy is not listed among the substituents for Ring A in Applicants’ claims 6 and 7.

The species listed on page 14, lines 11-12, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-hydroxyphenyl]benzenesulphonamide, and the species listed on page 14, lines 13-14 of Calderwood et al., N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-hydroxyphenyl]-4-*tert*-butylbenzenesulphonamide, do not anticipate Applicants’ claims 6 and 7 because in both of Calderwood et al.’s compounds the phenyl group which corresponds to Applicants’ Ring A is substituted by hydroxy. Hydroxy is not listed among the substituents for Ring A in Applicants’ claims 6 and 7.

Based upon the foregoing, the rejection of claims 6 and 7 under 35 U.S.C. §102(a) over Calderwood et al., WO 98/41525 is obviated and should be withdrawn.

The Examiner has rejected claims 6 and 7 under 35 U.S.C. §102(e) as allegedly being anticipated by Calderwood et al., U.S. Patent No. 6,001,839 (filed March 17, 1998). The Examiner alleges that “the instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., col. 10, lines 5-15, 26-27, 30-31 etc. The instant claims include ring A to be substituted by R_c which is defined to be –W-(CH₂)_t-O-alkyl or –W-(CH₂)_t-OH wherein W is a bond and t is 0, which compounds are identical to the reference disclosed compounds.” Applicants respectfully traverse this rejection.

The species listed at column 10, lines 5-6, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl]benzamide, lines 9-10, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl]benzenesulphonamide, and lines 26-27, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-methoxyphenyl]-4-*tert*-

butylbenzene-sulphonamide, of U.S. Patent No. 6,001,839 do not anticipate Applicant's claims 6 and 7 because in all of Calderwood et al.'s compounds the phenyl group which corresponds to Applicants' Ring A is substituted by methoxy. Methoxy is not listed among the substituents for Ring A in Applicants' claims 6 and 7.

The species listed at column 10, lines 7-8, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimdin-5-yl)-2-hydroxyphenyl]benzamide, lines 11-12, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimdin-5-yl)-2-hydroxyphenyl]benzenesulphonamide, lines 13-14, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimdin-5-yl)-2-hydroxyphenyl]-4-tert-butylbenzenesulphonamide, and lines 30-31, N-[4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimdin-5-yl)-2-hydroxy-phenyl]-4-chlorobenzamide of U.S. Patent No. 6,001,839 do not anticipate Applicants' claims 6 and 7 because in all of Calderwood et al.'s compounds the phenyl group which corresponds to Applicants' Ring A is substituted by hydroxy. Hydroxy is not listed among the substituents for Ring A in Applicants' claims 6 and 7.

Based upon the foregoing, the rejection of claims 6 and 7 under 35 U.S.C. §102(e) over Calderwood et al., U.S. Patent No. 6,001,839 is obviated and should be withdrawn.

The Examiner has rejected claims 1-8, 10 and 47 under 35 U.S.C. §103(a) over Calderwood et al., WO 98/41525. The Examiner alleges that "the reference teaches a generic group of compounds which is analogous to the instantly claimed compounds. See formula I in page 2 wherein R₃ is represented by formula (a) wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9); A is NHSO₂ (page 3, line 10) and R₅ is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23." Applicants respectfully traverse this rejection.

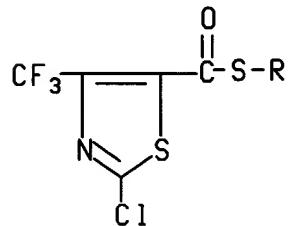
The Examiner has not established a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference. The reference does not provide any suggestion or motivation to modify WO 98/41525 to arrive at Applicants' genus. As discussed above in the traversal of the rejection of claim 46 under 35 U.S.C. §103 (a) over Calderwood et al., WO 98/41525, the Court of Appeals for the Federal Circuit has stated that there must be some teaching or suggestion supporting the modification.

In making a *prima facie* obviousness determination, an invention must be considered as a whole. In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).

Even in a case where the structural similarity was close, the CAFC has stated that a definite suggestion is needed in order to make the modification to establish a *prima facie* case of obviousness. In In re Grabiak the CAFC stated that "there must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant." In re Grabiak, 226 USPQ 870, 872, 1985.

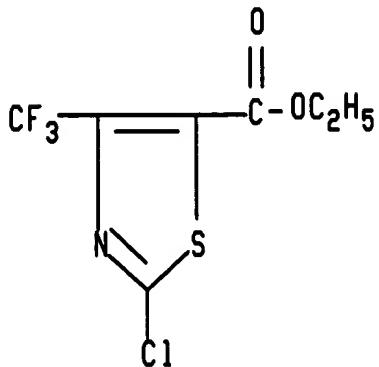
The Grabiak court made the above statement in light of the fact that both appellant's compounds and the prior art compounds were very similar in structure (see below) and had the same utility, namely, as herbicidal safeners.

Grabiak's Compound:



wherein R is C₁₋₅ alkyl, phenyl or benzyl

Howe's (prior art) Compound:



Note that when the R substituent is ethyl in the Grabiak compound, that the only difference in structure between Grabiak and Howe is a single atom, namely, an oxygen atom versus a sulfur atom. Hence, structural similarity and identical utility on its own cannot be the sole basis for a rejection under 35 U.S.C. § 103. Yet, the Examiner's rejection in the instant application under 35 U.S.C. § 103 does just that.

The Examiner has not shown that WO 98/41525 renders obvious the entire genus of Applicants' claims 1-8, 10 and 17. Applicants maintain that WO 98/41525 does not render claims 1-8, 10 and 17 obvious. WO 98/41525 does not teach or suggest all of the limitations of Applicants' claims. First as to the Examiner's contention that WO 98/41525 discloses several species that fall within the above genus, particularly page 14, lines 9-14 and 22-23. As addressed above in response to the 102(a) rejection, the species on page 14, lines 9-14 and 22-23 of WO 98/41525 do not fall within Applicants' genus of claims 1-8, 10 and 17 because each of these species contains a substituent on the phenyl group equivalent to Applicants' Ring A which is not included in Applicants' genus.

The Examiner has not shown that WO 98/41525 provides any suggestion or motivation to one of ordinary skill in the art to make Applicants' genus as it appears in claims 1-8, 10 and 47. Nor has the Examiner shown that WO 98/41525 teaches or suggests all the variables of Applicants' genus as it appears in claims 1-8, 10 and 47.

Based upon the foregoing, the rejection of claims 1-8, 10 and 47 under 35 U.S.C. §103(a) over Calderwood et al., WO 98/41525, is obviated and should be withdrawn.

In view of the foregoing amendments and remarks, Applicants believe that claims 1-8, 10 and 46-52 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' agent at the number noted below.

Respectfully submitted,

Date: July 11, 2003

Gayle O'Brien

Gayle B. O'Brien
Agent for Applicants
Reg. No. 48,812

Abbott Bioresearch Center
100 Research Drive
Worcester, MA 01605
(508) 688-8053